REMARKS

The present Amendment is based on Applicants' Amendment mailed January 19, 2005, in response to the final Office Action, and addresses the issues raised in the final Office Action. The Amendment mailed January 19, 2005, was not entered because it allegedly raised new issues for search or consideration. Entry of the present amendment is respectfully requested.

Regarding the Amendments

Claims 2, 7 and 12 have been amended to particularly point out and distinctly claim that which Applicant regards as the invention. Amendments to the claims do not add new matter and are fully supported by the specification. Upon entry of the amendment, claims 2 and 5-14 will be pending, and claims 1 and 3-4 are cancelled.

Rejections under 35 U.S.C. § 112, second paragraph

The rejection of claims 2-14 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully traverse this rejection.

The Office Action states that claims 2-14 are indefinite because they recite terms "growth differentiation factor-5 (GDF-5)," "GDF-5 specific antibody," "the GDF-5 polypeptide," "specifically," "specific," "specificity," "altered expression," and "normal subjects," See page 2 of the Office Action.

Claim 2 has been amended to more clearly define the metes and bounds of the claimed invention. Claim 2 recites a method of detecting expression of growth differentiation factor-5 (GDF-5) from uterine neoplasm, endometriosis or skeletal tissue by detecting levels of antibody binding of GDF-5 polypeptides having SEQ ID NO:10 and SEQ ID NO:13 amino acid sequences as compared to antibody binding to polypeptides in the control group. For example, reference to a "GDF-5 specific antibody" has been deleted, and amended claim 2 now recites "an antibody that specifically binds a GDF-5 polypeptide..." Also, the term "specimens of normal subjects" has been deleted and replaced by "a control group specimen." As used in the field of

biological and chemical arts, "control" confers the following general meaning: "[i]n research, control subjects or control procedures permit comparison with experimental results." Further, "control group," has the general meaning of: "[a] group of subjects participating in the same experiment as another group of subjects, but which is not exposed to the variable under investigation." All definitions are cited from http://cancerweb.ncl.ac.uk/cgi-bin/omd?control+group, an on-line medical dictionary. Hence, the term "control group specimen" as recited in claim 2 has substantially the same general meaning as "control group" as defined above. The term "specimen" in claim 2 refers to "uterine neoplasm tissue or endometriosis tissue or skeletal tissue," which is definite and unambiguous.

In view of the amendments and for the reasons set forth above, it is submitted that the skilled person would know the metes and bounds of the claimed subject matter. Accordingly, removal of the rejection of claims 2-14 under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 2-14 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for detecting altered expression of GDF-5 in a person in need thereof or in the subject suspected of having altered expression of the GDF-5. Applicants respectfully traverse this rejection.

The Office Action acknowledges that the specification is "enabling for a method of detecting GDF-5 having an amino acid sequence as set forth in SEQ ID NO:10 or SEQ ID NO:13 in uterine, endometrial, or skeletal tissue (see page 6 of Office Action)." Claim 2 has been amended to specifically define the origins of the specimen tissue, which "is from uterine neoplasm tissue or endometriosis tissue or skeletal tissue," and claims 3 and 4 have been cancelled and incorporated into amended claim 2. Hence, after amendment of the claims, the rejection of lack of enablement is moot, since the Office Action admits to the enablement of the claimed invention on page 6 (and as stated above).

The claimed invention, is fully supported by the specification. For example, support for enablement of claim 2 is found throughout the specification, in particular, page 6, lines 3-5, and 20; page lines 2-4, 6-7, Example 3, page 27, first paragraph and page 28, last paragraph; and Example 4, second paragraph. One means of determining the adequacy or sufficiency of a description to provide enablement of a claimed invention is to apply the factors of In re Wands. In re Wands, 8 USPQ 2d 1400 (Fed. Cir. 1988). Typically if the eight factors of In re Wands are satisfied, there is the presumption that no more undue experimentation is required, and the claimed invention is enabled by the description in the specification. Applicants argue that all eight factors of In re Wands are satisfied with regards to amended claim 2 and dependent claims thereof.

The eight factors of In re Wands are: (1) quantity of experimentation; (2) amount of guidance; (3) presence or absence of working examples; (4) nature of the invention; (5) state of prior art; (6) relative skill of those in the art; (7) predictability and unpredictability; and (8) breadth of the claims.

The quantity of experimentation (1) necessary to practice the claimed invention is no more than what is routine for the art. That is the methodologies required to practice the invention are standard in the art (e.g. DNA sequencing; deduction of amino acid sequence from the nucleotide sequence and whether it contains SEQ ID NOs:10 and 13 sequences; immuno-histochemistry using an antibody which binds to a polypeptide having the above-identified sequence; comparing levels of binding between the experimental and control group, etc.), and one skilled in the art can practice the invention from reviewing the specification. There is more than sufficient guidance (2) in the specification for one skilled in the art (i.e. at least four working Examples). Examples 1-4 provide working examples (3) to guide one skilled in the art to practice the invention. The nature of the invention (4) is detection of a polypeptide in a particular tissue using an antibody and comparing the same with a control group. The state of the prior art (5) with regards to methods for practicing the invention is well understood and well known to one skilled in the art. The relative skill of those in art (6) is high, as it is for research in the fields of molecular and biochemistry. Even with the high level of skill, the level of guidance

provided in the invention is such that there is a high level of predictability in both the methods and the results. Factors (1) through (6) all establish that the invention is highly predictable and any other experimentation which is not specifically disclosed in the invention is merely routine on the part of one skilled in the art. Lastly, the breadth of the claims (8) is not overly broad, and as amended, the claims clearly and unambiguously define the metes and bounds of the claimed subject matter. Thus, application of the eight factors of In re Wands are satisfied and no undue experimentation is required on the part of one skilled in the art.

For the above reasons, it is submitted that the specification enables one skilled in the art to practice the claimed invention without undue experimentation. Accordingly, removal of the rejection of claims 2 and 5-14 under 35 U.S.C. § 112, first paragraph, is respectfully requested.

In view of the amendments and the above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect respectfully is requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

If any additional fee is required in connection with the filing of this paper, the Commissioner is hereby authorized to charge any required fee associated with the filing submitted herewith, or credit any overpayments, to Deposit Account No. 07-1896.

Respectfully submitted,

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